**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

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| BRENDA REED AND RONALD REED,<br><br>Plaintiffs,<br><br>-against-<br><br>PFIZER, INC. AND WYETH LLC,<br><br>Defendants. | **MEMORANDUM & ORDER**<br><br>10-CV-05356 (ENV) (RER) |

**VITALIANO, D.J.**

Plaintiffs Brenda and Ronald Reed, citizens of West Virginia, commenced this action on November 19, 2010 seeking damages resulting from Ms. Reed's ingestion of Lybrel, an oral contraceptive pill allegedly designed, developed, and sold by defendants Pfizer, Inc. ("Pfizer") and Wyeth LLC ("Wyeth"). On January 20, 2011, defendants filed a letter requesting a pre-motion conference and permission to file a motion to dismiss. In that letter, defendants argued that plaintiffs' complaint should be dismissed based on a failure to plead plausible claims. The Court held the requested pre-motion conference on February 8, 2011. At that conference, "plaintiffs acknowledged that the complaint allowed room for further factual details." (Plaintiffs' Opposition, at 1.) The Court provided plaintiffs 30 days to file an amended complaint, which plaintiffs did do on the thirtieth day.

Defendants now move to dismiss the amended complaint for failure to state a claim upon which relief can be granted, arguing that, like the original complaint, the amended complaint fails to state plausible claims. Plaintiffs oppose defendants' motion, but as an alternative, seek leave to amend their pleadings yet again.

For the reasons recounted below, the motion to dismiss is granted without prejudice, and

with leave to amend.

## I. BACKGROUND[1]

In early 2009, Ms. Reed was prescribed Lybrel to alleviate heavy menstrual periods. (Plaintiffs' Amended Complaint ("Compl.") at ¶15.) Shortly thereafter, she began ingesting Lybrel, one dose per day. (Id. at ¶ 16.) The complaint concludes that, "[a]s a direct and proximate result of ingesting Lybrel, [Ms. Reed] developed deep vein thrombosis ("DVT"), pulmonary embolus, vein and tissue damage, severe pain in the left leg and right lung, difficulty breathing, and other serious injuries that required hospitalization, extensive testing, and other medical treatment." (Id. at ¶ 19.) Ms. Reed, it is further alleged, "has been incapacitated from her normal functioning" and "will require lifelong medical care and attention." (Id. at ¶ 20.)

Furthermore, plaintiffs allege, inter alia, (1) defendants knew or should have known that Lybrel was "negligently created, formulated, designed, manufactured, tested, and marketed, that the drug was not accompanied by adequate warnings; that medical professionals were prescribing the drug for non-approved uses; and that the drug was otherwise negligently and recklessly advertised, marketed, promoted, distributed, and sold," and (2) defendants "improperly obtained the approval of the FDA to market Lybrel by misrepresenting the risks of the drug to the FDA and/or by failing to inform the FDA of risks inherent in the use of the drug," and that such misrepresentations "deprived [Ms. Reed] of the opportunity to make an informed choice regarding the risks and benefits associated with" Lybrel. (Compl. at ¶¶ 10, 14, 23.)

## II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." This rule does not compel a litigant to supply

[1] The background facts are drawn from plaintiffs' pleadings and are considered true for purposes of this motion.

"detailed factual allegations" in support of his claims, Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964 (2007), "but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009). "A pleading that offers 'labels and conclusions' . . . will not do." Id. (quoting Twombly, 550 U.S. at 555); see also In re NYSE Specialists Sec. Litig., 503 F.3d 89, 95 (2d Cir. 2007). "Nor does a complaint suffice if it tenders 'naked assertions' devoid of 'further factual enhancement.'" Iqbal, 129 S. Ct. at 1949 (quoting Twombly, 550 U.S. at 557).

Moreover, under Rule 12(b)(6), a complaint must be dismissed if it does not "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. Determining plausibility is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. at 1950.

That said, the factual allegations are paramount as "a complaint need not pin plaintiff's claim for relief to a precise legal theory" nor provide "an exposition of his legal argument." Skinner v. Switzer, 131 S. Ct. 1289, 1296 (2011). In analyzing well-pled facts, a court will draw all reasonable inferences in favor of plaintiff. See Gorman v. Consol. Edison Corp., 488 F.3d 586, 591-92 (2d Cir. 2007). Of course, though a court must presume the truth of all factual allegations in the complaint for purposes of Rule 12(b)(6), the court is not bound to accept the truth of legal conclusions couched as factual allegations. Papasan v. Allain, 478 U.S. 265, 286, 106 S. Ct. 2932, 2944 (1986). Further, on a motion to dismiss, a court may only consider the pleading itself, documents that are referenced in the complaint, documents that the plaintiff relied on in bringing suit and that are either in the plaintiff's possession or that the plaintiff knew of when bringing suit, and matters of which judicial notice may be taken. See Chambers v. Time

Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002); Int'l Audiotext Network, Inc. v. Am. Tel.& Tel. Co., 62 F.3d 69, 72 (2d Cir. 1995).

Finally, should a court find pleadings to be inadequate, Rule 15(a) provides that the district court should freely grant leave to amend those pleadings when justice so requires. But, a district court correctly denies leave to amend "when an amendment is offered in bad faith, would cause undue delay or prejudice, or would be futile." Leonelli v. Pennwalt Corp., 887 F.2d 1195, 1198 (2d Cir. 1989) (citing Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 230 (1962)).

## III. DISCUSSION

The theories of liability initially relevant to determining whether plaintiffs have stated a viable claim are (1) failure to warn, (2) manufacturing defect, (3) design defect, (4) breach of express warranty, and (5) breach of implied warranty.[2] Lewis v. Abbott Labs., No. 08 Civ. 7480, 2009 WL 2231701, at *4-6 (S.D.N.Y. July 24, 2009) (cataloging various product liability theories and their redundancies); accord Morningstar v. Black and Decker Mfg. Co., 253 S.E.2d 666, 678, 681-83 (W.Va. 1979); Michael v. Wyeth, LLC, Civil Action No. 2:04–0435, 2011 WL 2150112, at *1-10 (S.D.W.Va May 25, 2011).

### A. Failure to Warn

To prevail on a failure to warn claim, a plaintiff must prove, "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." State Farm Fire

[2] Plaintiffs label their causes of action as "Negligence," "Strict Products Liability," "Negligence – Failure to Warn," "Breach of Express Warranty," "Breach of Implied Warranty," and "Loss of Consortium." Neither party addresses whether New York law or West Virginia law governs here. But defendants' citations to New York and West Virginia law for each potential cause of action implicitly represent the relevant law of the two states are equivalent for purposes of this motion. Further, plaintiffs either concede the same or represent that New York law governs, by relying exclusively on New York law when discussing the elements of the potential claims in their opposition.

& Cas. Co. v. Nutone, Inc., 426 F. App'x 8, 10 (2d Cir. 2011) (citing Liriano v. Hobart Corp., 92 N.Y.2d 232, 237, 700 N.E.2d 303 (1998)); accord Morningstar, 253 S.E.2d at 682-83. As part of satisfying those elements, a plaintiff is "required to prove that the product did not contain adequate warnings." Mulhall v. Hannafin, 45 A.D.3d 55, 841 N.Y.S.2d 282 (1st Dep't 2007). Following logically, a failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate. Bailey v. Janssen Pharmaceutica, Inc., 288 F. App'x 597, 608-09 (11th Cir. 2010) (affirming the dismissal of a failure to warn claim when the complaint "only assert[ed] that the warning was insufficient because it failed to warn of various dangers of the use of [the drug], without explaining either the information available to [the] physician at the time of the administration of the drug or how the contents of the label were inadequate"); Wendell v. Johnson & Johnson, No. C 09-04124, 2010 WL 271423, at *4 (N.D. Cal Jan. 20 2010) (dismissing a failure to warn claim because the plaintiffs "fail[ed] to allege how [the] warnings about [the drug] were inadequate"); Mills v. Bristol-Myers Squibb Co., No. CV 11–968, 2011 WL 3566131, at *3 (D. Ariz. Aug. 12, 2011) (dismissing a failure to warn claim because (1) plaintiff did not "plead any facts about what the [drug] label said or how it was deficient;" and (2) "the warning did describe a risk of [the alleged injury]").

Plaintiffs describe Ms. Reed's injuries as "deep vein thrombosis ("DVT"), pulmonary embolus, vein and tissue damage, severe pain in the left leg and right lung, difficulty breathing, and other serious injuries that required hospitalization, extensive testing, and other medical treatment." (Compl. at ¶¶ 19.) In contrast with their thorough recitation of Ms. Reed's claimed injuries, plaintiffs plead nothing about the content of Lybrel's warnings. This is likely because, as defendants note by reference to the FDA's website, Lybrel's FDA-approved warning labels

warn of the very injuries plaintiffs have pled.[3] Plaintiffs have not contested the authenticity of these FDA warnings despite having had an opportunity to do so. In that regard, the Court takes judicial notice that the warnings advanced by defendants are the FDA-approved warnings for Lybrel.[4] See Kramer v. Time Warner Inc., 937 F.2d 767, 774 (2d Cir. 1991) (holding district courts may take judicial notice of the contents of certain public records); Muller-Paisner v. TIAA, 289 F. App'x 461, 466, n. 5 (2d Cir. 2008) (holding that judicial notice "may be taken of the defendants' website for the fact of its publication"); Anspach ex rel. Anspach v. City of Philadelphia, Dept. of Public Health, 503 F.3d 256, 273 n. 11 (3d Cir. 2007) (taking judicial notice of an FDA publication, "not for the truth of its contents, but rather as evidence of the information provided by the federal government to healthcare providers").

Given all of this, the Reeds fall short of stating a failure to warn claim because the amended complaint does not allege facts identifying how the provided warnings were inadequate. Instead it first alleges (1) "the drug was not accompanied by adequate warnings;" and (2) the drug was promoted "without sufficient disclosure of its dangerous propensities." (Compl. ¶¶ 10, 14.) But assertions that warnings were not "adequate" or "sufficient" are nothing more than legal conclusions unsupported by factual content. The fact gap is never closed. The

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[3] (E.g., Vicari Dec., Ex. B at 10 ("An increased risk of venous thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established"); at 25 ("the following medical conditions have been associated with or made worse by the pill ... Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), stoppage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack and angina pectoris) or other organs of the body"); at 35 ("Blood clots and blockage of blood vessels are the most serious side effects of taking oral contraceptives and can cause death or serious disability. In particular, a clot in the legs can cause thrombophlebitis and a clot that travels to the lungs can cause a sudden blocking of the vessel carrying blood to the lungs"); at 38 ("[i]f any of [the following] adverse effects occur while you are taking oral contraceptives, call your health care professional immediately: ... sudden shortness of breath (indicating a possible clot in the lung) ... Pain in the calf (indicating a possible clot in the leg)....")

[4] To be clear, the Court does not take judicial notice of the truth, accuracy, or sufficiency of these warnings.

complaint runs on merely to allege (1) defendants "misrepresent[ed] the risks of the drug to the FDA and/or fail[ed] to inform the FDA of risks inherent in the use of the drug;" and (2) the "warnings and information given to the medical community and women consumers did not accurately reflect the symptoms, duration, scope, or severity of the potential side effects, health concerns, and risks associated with ingesting Lybrel." (Compl. ¶¶ 14, 40.) These additional allegations are simply not "enough to raise a right to relief above the speculative level" since they do not include "enough factual matter (taken as true) to suggest that a [misrepresentation] was made." Twombly, 127 S.Ct at 1965. Pointedly, these allegations do not include any factual content regarding what the misrepresentations were or how the provided warnings and information failed to "accurately reflect" reality; they do not provide a plausible basis to support an inference that Pfizer and Wyeth misrepresented anything.[5] Iqbal, 129 S.Ct. at 1949.

To cut to the chase, the fact (taken here as true) that Ms. Reed suffered from certain conditions that were also identified risks of ingesting Lybrel is tragic, but cannot *alone* make plausible a claim that defendants misrepresented or hid those risks in some way. Plaintiffs have alleged factual content sufficient only to make plausible that Ms. Reed ingested Lybrel and thereafter suffered serious harm. If such allegations were sufficient to state a failure to warn

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[5] The Court agrees with plaintiffs' argument that Twombly did not impose a pleading standard beyond that required by Rule 8, and that plaintiffs are thus required only to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." FRCP 8(a). see Arista Records, LLC v. Doe 3, 604 F.3d 110, 119 (2d Cir. 2010) ("[T]he notion that Twombly imposed a heightened standard that requires a complaint to include specific evidence, factual allegations in addition to those required by Rule 8, and declarations from the persons who collected the evidence is belied by the Twombly opinion itself."). But, at the same time, and apparently overlooked by plaintiffs, Twombly quite clearly interpreted the language of Rule 8 as requiring allegations to be plausible. Twombly, 550 U.S. at 557 ("The need at the pleading stage for allegations plausibly suggesting (not merely consistent with) [wrongdoing] reflects the threshold requirement of Rule 8(a)(2) that the 'plain statement' possess enough heft to 'sho[w] that the pleader is entitled to relief.'"); Arista Records, 604 F.3d at 120 ("The Twombly plausibility standard ... applies to all civil actions.") (citing Iqbal, 129 S.Ct. at 1953).

claim, then anyone experiencing harm after using a product where the harm is a warned-of risk could successfully plead a claim. Perversely, the pleaded fact that a warning was given would be the only pleaded fact supporting the claim that a lawfully adequate warning was not given. See Salvio v. Amgen Inc., No. 2:11-cv-00553, 2012 WL 517446, *6 (W.D.Pa Feb. 15, 2012) (dismissing a failure to warn claim because the "warning provided by Defendants advised Decedent's prescribing physicians of the very injury that occurred.") To allow such a naked claim to go forward would merely green light for plaintiffs an expedition designed to fish for an "*in terrorem* increment of the settlement value, rather than a reasonably founded hope that the discovery process will reveal relevant evidence." Dura Pharmaceuticals, Inc. v. Broudo, 544 U.S. 336, 347, 125 S.Ct. 1627 (2005) (quoting Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 741, 95 S.Ct. 1917 (1975)).

Accordingly, the Court finds that plaintiffs have not plausibly pled a failure to warn claim in their amended complaint. Indeed, the facts before the Court are that defendants did warn of the relevant risks. Plausibility requires some factual assertions as to how or why the acknowledged warning was inadequate, that is, about what risk of harm, or in what way, the acknowledged warning failed to warn.

**B. Manufacturing Defect**

A manufacturing defect claim is premised on the relevant product being defective because it was not manufactured as designed. See Am. Guarantee & Liab. Ins. Co. v. Cirrus Design Corp., No. 09 Cv. 8357, 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010); Morningstar, 253 S.E.2d at 681. Consistent with that premise, a manufacturing defect claim is properly dismissed if a plaintiff has not alleged "that the particular [drug] administered to her had a defect as compared to" other samples of that drug. Lewis, 2009 WL 2231701, at *2.

Plaintiffs fail to plead any facts making such an allegation. Rather, they merely plead the legal conclusions that defendants were (1) "negligent" in "formulating" "fabricating," "manufacturing," and "packaging," Lybrel; (2) did so "in violation of applicable statutes, regulations, and appropriate standards of care;" and (3) "failed to perform sufficient and necessary testing that would have shown Lybrel's defective condition." (Compl. at ¶¶ 23, 29, 30.) By not pleading facts indicating how or why the Lybrel ingested by Ms. Reed differed from its design, plaintiffs have not enabled the Court "to draw the reasonable inference that the defendant[s are] liable for the misconduct alleged." Iqbal, 129 S. Ct. at 1949 (quoting Twombly, 127 S. Ct. 1955). The manufacturing defect claim does not survive pleading.

**C. Design Defect**

A design defect claim, on the other hand, is premised on a manufacturer's failure to properly design a product, which is then placed on the market despite posing inappropriate risks. Voss v. Black & Decker Mfg., 59 N.Y.2d 102, 107 (N.Y. 1983). Morningstar, 253 S.E.2d at 681. Again, eschewing the opportunity to plead facts identifying Lybrel's design defect, the Reeds merely plead the legal conclusion that the Lybrel was defective. (Compl. at ¶¶ 10, 13) ("Defendants knew ... the drug was negligently ... designed," and that "the benefits of using Lybrel, if any, did not outweigh the risks inherent in the use of the drug.") Such pleadings are subject to dismissal. Lewis, 2009 WL 2231701, at *4 (dismissing a claim alleging that a drug was "inherently dangerous" and had "side effects outweigh[ing] its benefits," without also pleading factual content in support of those allegations).

Plaintiffs' design defect claim also fails for an additional reason. Plaintiffs do not plead facts alleging the existence of a feasible alternative design that would make the product safer, as is required to establish a design defect, under either New York or West Virginia law. Voss, 59 N.Y.2d at 108. Church v. Wesson, 385 S.E.2d 393, 396 (W. Va. 1989). As a result of such a

failure, the claim is subject to dismissal. Lewis, 2009 WL 2231701, at *4 (finding a plaintiff did not "meet her burden to allege evidence that [a drug] is not reasonably safe" because "plaintiff has not alleged that it was feasible for [the manufacturer] to design [the drug] in a safer manner"); Am. Gaurantee & Liab. Ins. Co., No. 09 Cv. 8357, 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30 2010) (dismissing a design defect claim because plaintiff did not plead, inter alia, "a feasible alternative design"). The complaint, as a consequence, does not validly plead a design defect claim.[6]

**D. Breach of Express and Implied Warranties**

Any "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." N.Y.U.C.C. §2-313(1)(a); W. Va. Code, § 46-2-313(1)(a). A successful claim of a breach of express warranty requires proof that an express warranty existed, was breached, and that plaintiff had relied on that warranty. Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 285-86 (E.D.N.Y 2009); Horan v. Turnpike Ford, Inc., 433 S.E.2d 559 (W. Va. 1993). Further, a successful breach of warranty claim requires that the product be defective. Plemmons v. Steelcase Inc., No. 04 Civ. 4023, 2007 WL 950137, at *5

[6] To the extent a negligence claim could exist independently from, or as part of, any claims discussed above, it fails because plaintiffs have not pled factual content sufficient to create a plausible inference that defendants breached any duty they owed to Ms. Reed. Specifically, the Reeds have not pled facts making it plausible (1) that anything that defendants did or failed to do fell below the standard of reasonable care or (2) that the Lybrel was defective in any way including in its warnings, manufacture, or design. See Am. Gaurantee & Liab. Ins. Co., 2010 WL 5480775, at *4 (explaining that "to recover in negligence under New York law, a successful plaintiff must demonstrate the existence of a duty, the breach of which may be considered the proximate cause of the damages suffered by the injured party" and finding a complaint did not adequately plead negligence because it did "not contain sufficient facts to establish either knowledge of a defect on the part of [the defendant] or anything that [defendant] did that fell below the standard of reasonable care that rendered the [product] defective"); Parsley v. General Motors Acceptance Corp., 280 S.E.2d 703 (W.Va 1981) (explaining that "to establish a prima facie case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the plaintiff").

(S.D.N.Y, March 29, 2007) (citing Tardella v. RJR Nabisco, Inc., 178 A.D.2d 737, 737 (N.Y. App. Div.3d Dep't 1991)).

Plaintiffs fail to state an express warranty claim for reasons similar to why they did not meet the standard for a failure to warn claim, a design defect claim, and a manufacturing defect claim. The allegations are not sufficient to draw a reasonable inference that (1) Lybrel was defective or (2) what defendants promised was different than what they provided.[7] Plaintiffs' unsupported conclusions that Lybrel differed in some defective manner from what was warranted lack the required factual content identifying that difference and making its existence plausible.

Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 285 (E.D.N.Y 2009) is instructive here. The Horowitz court dismissed an express warranty claim (relating to a failure of an artificial hip) because, inter alia, the plaintiff did "not even describe how [the allegedly breached] representation was made." 613 F. Supp. 2d at 286. In holding so, the court distinguished Huber v. Howmedica Osteonics Corp., No. 07-2400, 2008 WL 5451072 (D.N.J. Dec. 31, 2008), a case in which a plaintiff was found to have properly stated a breach of express warranty claim regarding the same type of artificial hip at issue in Horowitz. The Huber plaintiff alleged "the existence of evidence showing that the .5% defect rate printed on the [artificial hip's] label is actually much higher and that the defect rate was a basis of the bargain." Horowitz, 613 F. Supp. 2d 286, n. 8 (discussing Huber). As in Horowitz, and unlike in Huber, the Reeds have not

[7] In addition to allegations discussed above, the amended complaint includes supplemental allegations relevant to the warranty claims: (1) defendants "warranted that Lybrel had been adequately tested for its intended use, that it was of merchantable quality, and that it was safe and suitable for use by women as a daily oral contraceptive medication that would prevent pregnancy and eliminate menstrual bleeding;" (2) the warranty was relied upon by the medical community (presumably including Ms. Reed's doctor); (3) defendants knew or should have known that the alleged warranty was false "in that Lybrel was not reasonably safe and fit for its intended use, and was not of merchantable quality, [and] ... causes or contributes to serious adverse health effects, risks, complications, and other injuries;" and (4) defendants "knew or should have known that approximately half of the women who take Lybrel will not experience cessation of menstrual bleeding." (Compl. at ¶¶ 47-50.)

alleged factual content sufficient for the Court to reasonably infer defendants breached any representation of fact or promise. Plaintiffs have alleged nothing which makes plausible that Lybrel's various risks differ from what was warranted.[8]

For largely the same reasons, the Court finds plaintiffs have also failed to plead a proper breach of implied warranty claim. Saratoga Spa & Bath v Beeche Sys. Corp., 230 A.D.2d 326, 330, 656 N.Y.S.2d 787 (3d Dep't 1997) ("The implied warranty of merchantability is a guarantee by the seller that its goods are fit for the intended purpose for which they are used and that they will pass in the trade without objection ...[an implied warranty claim] cannot arise unless the goods sold are not of merchantable quality. For goods to be of merchantable quality they need to be reasonably fit for their intended purpose; they need not, however, be perfect."); N.Y.U.C.C. §2-314; W. Va. Code, § 46-2-314. Viewed in this light, plaintiffs have not pled facts making it plausible that Lybrel was not fit for its intended purpose.

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[8] Plaintiffs' factually consistent but conversely stated allegations that (1) "Defendants knew or should have known that approximately half of the drug's users would experience cessation of menstrual periods, Compl. at ¶ 11, and (2) "Defendants knew or should have known that approximately half of the women who take Lybrel will not experience cessation of menstrual bleeding," Compl. at ¶ 50, lack relevance because these broadly stated allegations are consistent with Lybrel's FDA-approved warning labels. (Vicari Dec., Ex. B at 27) ("In a study of LYBREL, about 5 out of 10 women had 7 or more days of bleeding or spotting while using their third 28-day pill pack of LYBREL. The number of women with 7 or more days of bleeding or spotting decreased to 3 out of 10 women during the use of their seventh pill pack. Among women who continued to use LYBREL for one year, about 6 out of 10 women had no bleeding or spotting during their last month of use ... MOST WOMEN HAVE SPOTTING OR BLEEDING DURING THE FIRST FEW MONTHS OF TAKING *LYBREL*") (emphasis in original). To the extent an inconsistency between Lybrel's warnings and defendants' actual knowledge existed regarding the drug's effect on menstrual bleeding, the amended complaint does not adequately identify it. Moreover, regarding reliance on any warranty (and causation in her other claims), the amended complaint does not relate plaintiffs' allegations of Lybrel's ability to cause "cessation of menstrual periods" to Ms. Reed's stated reason for taking Lybrel, i.e., "to alleviate severely heavy menstrual periods." (Compl. at ¶ 15.)

## E. Leave to Further Amend is Granted[9]

Plaintiffs have already attempted, but failed, to overcome pleading inadequacies previously identified. At the same time, what has been previewed in the amended complaint suggests that, with guidance from this Memorandum and Order, that plaintiffs may yet be able to plausibly re-plead at least some of their claims. The Court, as a result, grants leave to amend one more time. In exercising its discretion to do so, the Court has considered the high value to be placed on merit resolution of cases and controversies. Plaintiffs are advised that, given the Court's specific identification of pleading shortcomings, failure to address them successfully in the next round will not likely be rewarded with a third opportunity to cure.

## IV. CONCLUSION

For the foregoing reasons, all claims against defendants are dismissed without prejudice and with leave to amend. The second amended complaint shall be filed within 30 days of the date this order is entered on the docket.

SO ORDERED.

Dated: Brooklyn, New York
March 14, 2012

s/ENV

ERIC N. VITALIANO
United States District Judge

[9] The loss of consortium claim is derivate, and therefore dismissed pro tanto. See Lake v. Kardjian, 874 N.Y.S. 2d 751, 755 (Supp. Ct. 2008); Davis v. Foley, 457 S.E.2d 532, 535 (W. Va. 1995).